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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,379	01/09/2002	Jonathan Luke Heeney	294-105PCTUS	1582

7590  
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11/06/2002

EXAMINER
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MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/06/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/890,379

Applicant(s)

Heeney et al

Examiner

Mosher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 8/26/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 29-45 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No.(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No.(s). \_\_\_\_\_ 6) ☐ Other:

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*Claim Rejections - 35 USC § 102*

Claims 29, 31, 34, 35, 37-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Ertl 6,210,663. Ertl teaches sequential immunization using a DNA plasmid vector followed by an adenovirus vector, see e.g. example 3 starting at column 21. Ertl indicates that this induces a Th1 response, see column 23 lines 6-14 and the passage spanning columns 14-15. Ertl also teaches adding an immune response modulator coding sequence, see example 5 starting at column 23. Therefore the reference meets each and every claim limitation.

*Claim Rejections - 35 USC § 103*

Claims 32, 33, and 36 rejected under 35 U.S.C. 103(a) as being unpatentable over Ertl 6,210,663. These claims differ from the above in specifying a lentivirus antigen or an antigen from an immune-impairing virus. Ertl discusses HIV as a suitable virus target for the disclosed immunization method, see column 1, line 59; it would have been obvious to choose one of the known HIV antigenic proteins as an obvious variation on the disclosed immunization method, for the purpose of inducing a desirable mucosal immune response directed against HIV. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Claims 30 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ertl 6,210,663 in view of Pachuk et al. As discussed above, Ertl provides working examples of sequential immunization using a DNA plasmid vector followed by an adenovirus vector, which induce a Th1 response. These claims differ from Ertl in requiring a third vector for administration. Pachuk teaches a nucleic acid vaccination method, where modifications of the antigen coding

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sequence control Th1 or Th2 response. Pachuk suggests using a primary and first boost to induce a Th1 response, and a second boost to drive a Th2 response, thus affording the vaccinee improved protection. See for example column 4, lines 35-41. Since the method of Ertl induced mainly a Th1 response, one skilled in the art would have been motivated to modify Ertl by administering a second booster designed for driving a Th2 response, to obtain improved protection as suggested by Pachuk. Since Ertl teaches that it is desirable to avoid an anti-viral immune response to the boosting virus vector (see Abstract, for example), it would have been obvious to choose for the second booster "...another virus that can be employed as the carrier portion of the boosting composition...e.g. a recombinant vaccinia, retrovirus, or an avian poxvirus" (column 13, lines 29-32) to avoid an anti-viral immune response to a second booster. Therefore, the invention as a whole is seen as prima facie obvious, absent unexpected results.

#### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November 6, 2002

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800**

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